AUG - 9 2001

K003714

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Integration Diagnostics Ltd. summary for the Osstell™ RFA.

SUBMITTER'S NAME:	Integration Diagnostics Ltd.
ADDRESS:	Göteborgsvägen 74 433 63 Sävedalen Sweden
CONTACT PERSON:	Constance Bundy
TELEPHONE NUMBER:	763-574-1976
FAX NUMBER:	763-571-2437
DATE OF SUBMISSION:	December 1, 2000

1. **Identification of device**
   Proprietary Name: Osstell™ Resonance Frequency Analyzer
   Common Name: Dental implant stability analyzer
   Classification Status: This specific type of device has not been classified. The predicate device was Class II per regulation 872.4200, product code EKX.

2. **Equivalent devices**
   Integration Diagnostics Ltd. believes the Osstell is substantially equivalent to Periotest, cleared for marketing under 510(k) K872171.

3. **Description of the Device**
   Osstell™ RFA is intended for measuring the stability of implants in the oral cavity and craniofacial region. It can be used as a portable, handheld or freestanding instrument and patient data can be downloaded to a PC. The system comprises three main components; the Instrument, the Transducer and the PC data manager software.

   The Instrument is a compact unit with built in LCD graphical display. The unit operates from a rechargeable power source offering over 15 hours of continuous use between charges.

   Transducers are small electronic devices attached by screws to an implant fixture or abutment then plugged into the Instrument. They are individually made to be used with all major implant systems.

   The system is provided with an IrDa infrared link, a serial cable and software to enable data to be downloaded to a PC for storage on a database and subsequent analysis and printing.

4. Intended use

The Osstell RFA is intended for measuring the stability of implants in the oral cavity and craniofacial region.

5. Technological characteristics, comparison to predicate device

The Osstell RFA has no unique applications, indications, materials or functions. Evidence of equivalence has been demonstrated through:

- The Osstell RFA intended use is equivalent to the intended use of the predicate device, Periotest, cleared by FDA under 510(k) K872171.
- The function of the Osstell RFA and Periotest is similar in that they both use a form of vibration to assess implant stability.
- Both the Osstell RFA and Periotest devices are currently being used clinically to assess implant stability.
- Osstell RFA safety and performance testing.

7. Conclusion

It is the conclusion of Integration Diagnostics Ltd. that the Osstell RFA is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2001

Ms. Constance Bundy
Consultant
Integration Diagnostics Limited
6470 Riverview Terrace, Incorporated
Minneapolis, Minnesota 55432

Re: K003714
Trade/Device Name: Osstell Resonance Frequency Analyzer
Regulation Number: 872.4200
Regulatory Class: I
Product Code: EKX
Dated: August 1, 2001
Received: August 3, 2001

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number K003714

Device Name: Osstell™Resonance Frequency Analyzer

Indications for Use:

Osstell™Resonance Frequency Analyzer is intended for measuring the stability of implants in the oral cavity and craniofacial region. Osstell can add important information to the evaluation of implant stability and can be used as part of an overall treatment evaluation program. The final implant treatment decisions are the responsibility of the surgeon.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003714